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EUROPEAN COMMISSION

Brussels, 31-08-2010
C(2010)6115

COMMISSION DECISION

of 31-08-2010

**amending the marketing authorisation granted by Decision C(2004)3160 for
“Ariclaim - duloxetine hydrochloride”, a medicinal product for human use**

(ONLY THE DUTCH TEXT IS AUTHENTIC)

COMMISSION DECISION

of 31-08-2010

**amending the marketing authorisation granted by Decision C(2004)3160 for
“Ariclaim - duloxetine hydrochloride”, a medicinal product for human use**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency¹,

Having regard to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products², and in particular Article 20(7)(a) thereof,

Having regard to the application submitted on 25 April 2010 by Eli Lilly Nederland B.V. under Article 20(3) of Regulation (EC) No 1234/2008,

Having regard to the opinion of the European Medicines Agency, formulated on 22 July 2010 by the Committee for Medicinal Products for Human Use,

Whereas:

- (1) The European Medicines Agency has informed the marketing authorisation holder and the Commission of its favourable opinion on the group of minor variations and of the need to amend the marketing authorisation.
- (2) The marketing authorisation should be updated and Decision C(2004)3160 of 11 August 2004 should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.
- (3) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2004)3160 should therefore be replaced,

¹ OJ L 136, 30.4.2004, p. 1.

² OJ L 334, 12.12.2008, p. 7.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)3160 is amended as follows:

- 1) Annex I is replaced by the text set out in Annex I to this Decision;
- 2) Annex III B is replaced by the text set out in Annex III B to this Decision.

Article 2

This Decision is addressed to Eli Lilly Nederland B.V., Grootslag 1-5, 3991 RA Houten, Nederland.

Done at Brussels, on 31-08-2010.

For the Commission
Paola TESTORI COGGI
Director-General